REMARKS

Upon entry of the above amendments, claims 14-21 and 26-27 will be pending and under consideration.

Claim 22 has been canceled herein without prejudice, in view of the amendment to claim 14 discussed below.

Claim 14 has been amended herein for purposes of clarity. Claim 14 has been amended to recite that said binding-ready biological sample is a nucleic acid sample, and said binding assay is a hybridization assay. Support for this amendment to claim 14 is found in the specification as filed, *inter alia*, in Paragraph 0002 on page 1; in Paragraphs 0024 and 0025 on pages 4-5; and in Paragraph 0063 on page 13.

Claims 26 and 27 have been newly added. Support for new claim 26 is found in the specification as filed, *inter alia*, in Paragraph 0086 on page 19 and in Paragraph 0089 on pages 19-20. Support for new claim 27 is found in the specification as filed, *inter alia*, in Paragraph 30 on page 6.

No new matter is added by the amendments to the claims.

The Rejection under 35 U.S.C. § 102(e) For Lack Of Novelty Should Be Withdrawn

Claims 14-15 and 22 are rejected under 35 U.S.C. § 102(e), allegedly as anticipated by U.S. Patent No. 5,968,731 to Layne *et al.* ("Layne"). The Examiner alleges that Layne teaches the claimed computer implemented method for preparing a binding-ready biological sample for a binding assay as claimed in claim 14, teaches optimization of performing experiments as claimed in claim 15, and teaches a form of a binding assay that involves hybridization as claimed in claim 22.

Preliminarily, Applicants note that claim 22 has been canceled and claim 14 has been amended to incorporate the subject matter of claim 22, such that amended claim 14 now recites that said binding-ready biological sample is a nucleic acid sample, and said binding assay is a hybridization assay.

Layne discloses an automated apparatus and method for performing automated testing of infectious biological specimens, which includes a means for treating the specimen to manifest an observable result, which result is then measured. The apparatus and method disclosed in Layne are applied to the detection of infectious HIV in a cell sample, and involve infecting cells (via the infectron)[1], and detecting the infected cells by detecting (via the detectron)[2] HIV antigen via a HIV enzyme-linked immuno-sorbent assay (ELISA) or staining cell monolayers with anti-HIV immunoglobulins[3]. Layne discloses only antibody-based means to detect the presence of HIV[4]. There is no teaching in Layne of automated nucleic acid sample preparation for use in a hybridization assay. Applicants point out that an ELISA is not "a form of a binding assay that involves hybridization" as alleged by the Examiner. To the contrary, an ELISA is an assay involving antibody-antigen recognition, detected by use of an enzyme tag on a secondary or tertiary reactant. As evidence of the foregoing, the Examiner's attention is invited to Exhibit A, attached hereto, which is page 11-4 from Short Protocols in Molecular Biology, 4th Ed., Ausubel *et al.*, Eds., John Wiley & Sons, Inc., New York 1999. Exhibit A discloses that an ELISA is used to detect antigens or antibodies. In contrast, a hybridization assay involves nucleic acid-nucleic acid base pairing interactions. As evidence of the foregoing, the Examiner's attention is invited to Exhibit B, attached

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[1] Layne, column 11, line 47 to column 12, line 65

[2] Layne, column 13, lines 13-33

[3] Layne, column 13, lines 21-27

[4] Layne, column 13, lines 13-33

hereto, which is pages 202-203 from Molecular Cell Biology, 2nd Ed., Darnell *et al.*, Eds., Scientific American Books, New York 1990. Page 203, left column, states that "such *molecular hybridization* can take place between complementary strands of either DNA or RNA or between an RNA strand and a DNA strand (Figure 6-12)" (emphasis in original). Thus, as would be well known to one skilled in the art, an ELISA is not a hybridization assay.

The legal standard for anticipation under 35 U.S.C. § 102 is one of strict identity. A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently, in a single prior art reference. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987); *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). In other words, there must be no difference between the claimed invention and the reference disclosure as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). *See also, Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (stating that the "identical invention must be shown in as complete detail as is contained in the patent claim"). Since Layne teaches an ELISA and not a hybridization assay, and since the samples prepared by Layne are protein samples not nucleic acid samples, Layne cannot anticipate claim 14 as amended herein. Further, since Layne does not anticipate claim 14, Layne cannot anticipate claim 15, which depends from claim 14.

In view of the foregoing, Applicants respectfully submit that this rejection under 35 U.S.C. § 102(e) has been overcome. Therefore, Applicants respectfully request withdrawal of this rejection.

The Rejection under 35 U.S.C. § 103 For Obviousness Should Be Withdrawn

Claims 16-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,968,731 to Layne *et al.* ("Layne"). The Examiner alleges that although Layne does not explicitly teach the subject matters of claims 16-21, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the subject matters of claims 16-21 with the automated apparatus and method for performing automated testing of biological specimens, as taught in Layne.

A finding of obviousness under 35 U.S.C. § 103(a) requires a determination that the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966). The relevant inquiry is whether the prior art suggests the invention and whether the prior art provides one of ordinary skill in the art with a reasonable expectation of success. The Supreme Court recently ruled in *KSR International Co. v. Teleflex, Inc.* 127 S.Ct. 1727 (2007) that the Court of Appeals for the Federal Circuit had applied a too-rigid standard for determining obviousness under Section 103 of the Patent Act and held that the standard for determining obviousness was more expansive and flexible consistent with Supreme Court precedent. However, the Supreme Court also held that "[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art." *Id.* at 1731.

Furthermore, an analysis under 35 U.S.C. § 103(a) "should be made explicit," and "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* The Court went further to clarify that "this is so because inventions in most, if not

all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.*

Applicants respectfully disagree with the Examiner's rejection. As discussed above, claim 14 has been amended to recite that said binding-ready biological sample is a nucleic acid sample, and said binding assay is a hybridization assay. Further, as discussed above, Layne does not teach a hybridization assay. Layne discloses an ELISA, which is a protein-based immunological assay, to detect HIV antigens. Layne does not provide any suggestion that a nucleic acid-based hybridization assay could be substituted for a protein-based assay, nor does Layne give reason to substitute the ELISA with a hybridization assay, since, *e.g.*, Layne prepares protein samples not nucleic acid samples for detecting HIV. Since Layne does not suggest or give reason to prepare nucleic acid samples for use in a hybridization assay, Layne cannot render obvious the claimed computer implemented method for preparing a binding-ready biological nucleic acid sample for use in a hybridization assay, as claimed in claim 14. Since Layne does not render obvious the subject matter of claim 14, Layne cannot render obvious the subject matters of claims 16-21, which directly or indirectly depend from claim 14.

Also, Applicants note with regard to new claim 26 that Layne does not teach or suggest work instructions comprising instructions for pooling a plurality of binding-ready biological samples, nor does Layne give reason to pool a plurality of binding-ready biological samples. Layne discloses in column 7, line 52 to column 8, line 12 that the automated method is provided for automated analysis of the physical properties of individual isolates of HIV. Pooling individual samples would not allow for the determination of the physical properties of the individual viral isolates. Thus, the subject matter of claim 26 is not obvious in view of Layne.

Further, although Layne at column 11, line 24 mentions that the process control tool (PCT) implements functions related to the business aspect of the automated test facility, such as inventory management, Layne does not teach or suggest that its automated method includes a step of scheduling sample preparation for the binding assay while taking into account the relative priorities of experiments and availability of parts in inventory, nor does Layne give reason to include such a scheduling step. Thus, the subject matter of new claim 27 is not obvious in view of Layne.

In view of the foregoing, Applicants respectfully submit that this rejection under 35 U.S.C. § 103(a) has been overcome. Therefore, Applicants respectfully request withdrawal of this rejection.

CONCLUSION

Applicants respectfully request that the above-made amendments and remarks of the present response be entered and made of record in the file history present application. Applicants submit that the presently pending claims meet all requirements for patentability and respectfully request allowance and action for issuance.

Applicants request that the Examiner call the undersigned at (212) 326-3939 if any questions or issues remain.

Respectfully submitted,

Date: September 30, 2009

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